Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed Ultrasound Catheters

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- STERILE

Explanation of Symbols

℞Only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Catalogue Number
	Do Not Reuse
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	Non-Pyrogenic

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Catheter Description
Ultrasound Catheters are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer. The ultrasound transducer is at the distal tip of the catheter and can be positioned for ultrasound imaging by a steering mechanism that rotates the catheter tip and variable deflection. Ultrasound Catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer.

Indications for Use
Reprocessed Ultrasound Catheters are intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.
Note: The original manufacturer indications for use includes usage for pediatric population. The Stryker Sustainability Solutions indications for use does not specifically include usage for pediatric population but also does not contraindicate for pediatric population usage. The use of the device should be based on clinical judgment.

Contraindications for Use
Reprocessed Ultrasound Catheters are contraindicated for:
- Presence of conditions that create unacceptable risk during cardiac catheterization.
- Inadequate vascular access.
- Sepsis
- Major coagulation abnormalities
- Presence of any intracardiac thrombus
- Deep vein thrombosis
- Significant peripheral vascular disease
- Use in coronary vessels
- Insertion into the arterial system
- Fetal use
- Presence of class IV agina or heart failure

Warnings
- Ultrasound catheters should be used only by or under the supervision of an appropriately trained physician using proper procedures and techniques.
- Do not exert excessive pressure during placement of catheter if unknown resistance is encountered.
- Vascular damage, including perforation, is a small but inherent risk.
- Carefully manipulate the catheter in order to avoid cardiac damage, perforation or tamponade.
- If encountering strong resistance during catheter articulation, discontinue the procedure and determine the cause of the resistance before proceeding.

Precautions
- Do not attempt to use the Reprocessed Ultrasound Catheter prior to completely reading and understanding the *Directions for Use.*
- Inspect the packaging and catheter for damage or defects prior to use.
- Avoid excessive kinking or bending of catheter, as this may interfere with distal tip shaping.
- Ensure that the two articulation knobs are in the neutral position and the brake is released before advancing or withdrawing the ultrasound catheter.
- For proper care and handling of the ultrasound catheter, always hold the ultrasound catheter by the handle and support the catheter shaft. Avoid touching the ultrasound catheter interconnect tab.

Adverse Reactions

The following are known potential adverse reactions

- Pulmonary embolism
- Stroke
- Death
- Thrombosis
- AV fistula
- Air embolism
- Pneumothorax
- Valve or structural cardiac damage
- Myocardial infarction
- Tamponade
- Femoral artery or vein injury
- Pseudoaneurysm
- Cardiac perforation
- Hemothorax

Directions for Use

Before you begin the procedures, power on the ultrasound system

1. Inspect the connector for damage
2. Stryker will not accept catheters for reprocessing that have been reprocessed and sterilized by other facilities.
3. The catheter package label is detachable and may be affixed to the medical record of the patient.
4. Turn the ultrasound system on. Verify incoming main voltage is 120 V AC.
5. Inspect the catheter and package before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is damaged or if it was opened and the catheter not used, do not use the catheter. Return the catheter and packaging to Stryker Sustainability Solutions for resterilization by ethylene oxide (EtO) gas.
6. Do not attempt to resterilize. Using proper sterile technique, remove the catheter from the sterile package. Place the catheter in a sterile working area.
7. Inspect the entire catheter for damage.
8. Position the steering knobs in the neutral position by aligning the marks on the steering knobs to the marks on the housing.
9. Connect the system connector to the ultrasound system.
10. Slip the sterile sheath over the catheter interconnect tab until the sheath is fully seated on to the catheter handle.
11. Lift the lever on the connector. Slip the connector on to the catheter interconnect tab until the connector is fully mated with the catheter handle. Push the lever down, locking the catheter to the connector.
12. Carefully slip the sterile sheath over the connector. Cover enough of the connector so the connector is out of the sterile field.
13. Verify that the imaging screen appears.

During the Procedure

To conduct an ultrasound exam using the catheter:

1. Create a vascular access with a catheter introducer (hemostatic) large enough to accommodate the catheter with heparinized saline.
2. Before advancing or withdrawing the catheter, ensure that the steering knobs are in the neutral position and that the tension control knob is released.
3. Advance the catheter into the vasculature through the catheter introducer. Fluoroscopy can aid in advancing the catheter into the heart.
4. When the catheter is inside the heart, use the steering knobs to direct the ultrasound transducer to visualize the target cardiac anatomy.

Procedure Conclusion

To end an ultrasound exam using the catheter:

1. Before you withdraw the catheter, ensure that the steering knobs are in the neutral position and that the tension knob is released.
2. Withdraw the catheter from the patient

Compatibility

Model #	Ultrasound Connector Type	Ultrasound Console Type
10135910	Swift-link	GE (Vivid *i*, Vivid *q*)
10043342	Swift-link	GE (Vivid *i*, Vivid *q*)
10135936	Swift-link	Siemens/Acuson (Sequoia,Cypress, SC2000, X300, X700)
08255790	Swift-link	Siemens/Acuson (Sequoia, Cypress, SC2000, X300, X700)

Storage and Handling

- Store Reprocessed Ultrasound Catheters in a cool, dry place.
- Air freight only in pressurized cargo.
- Relative humidity: Up to 90% non-condensing.
- Temperature: Maximum 50°C (122°F), Minimum 10°C (14°F)

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LAIBLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL,

INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4)

products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.